

**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products  
Liability Litigation,

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No. MDL15-2641-PHX-DGC

Lisa Hyde and Mark Hyde,

Plaintiffs,

v.

C. R. Bard, Inc., a New Jersey corporation;  
and Bard Peripheral Vascular, Inc., an  
Arizona corporation,

Defendants.

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**THE PARTIES' JOINT SUBMISSION OF  
PROPOSED JURY INSTRUCTIONS**

Pursuant to the Court's direction, the parties are providing this joint submission regarding proposed jury instructions. The proposed instructions are organized as follows:

Exhibit "A": Attached as Exhibit "A" are the preliminary jury instructions used by the Court at the beginning of trial in the Booker case, revised only to reflect the parties and attorneys involved in the Hyde case. The parties are in agreement that these instructions should be given in Hyde as modified.

Exhibit "B": Attached as Exhibit "B" are the introductory and concluding instructions given by the Court in the Booker and Jones cases, as a part of the final jury instructions. The parties are in agreement that these instructions should also be given in the Hyde case, as a part of the final jury instructions.

Exhibit “C”: Attached as Exhibit “C” are the substantive law instructions that all parties agree should be given in Hyde.

Exhibit “D”: Attached as Exhibit “D” are the instructions disputed by the parties. Those instructions set forth the proposed instruction, the opposing parties’ objections, and the response.

RESPECTFULLY SUBMITTED this 29<sup>th</sup> day of August, 2018.

GALLAGHER & KENNEDY, P.A.

NELSON MULLINS RILEY &  
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s/ Mark S. O’Connor (with permission)

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 29th day of August, 2018, I electronically transmitted a PDF version of this document to the Clerk of the Court, using the CM/ECF System for filing and for transmittal of a Notice of Electronic Filing.

/s/ Jessica L. Gallentine

## **Exhibit “A”**

You are now the jury in this case and it is my duty to instruct you on the law. It your duty to find the facts from all of the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you, whether you agree with it or not, and you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that you took an oath to do so.

At the end of the trial, I will give you final instructions. It is the final instructions that will govern your deliberations and your duties as jurors.

Please do not read into these instructions or the final instructions or anything I may say or do that I have an opinion regarding the evidence or what your verdict should be.

To help you follow the evidence, I will give you a brief summary of the positions of the parties. This is a personal injury case against a medical product manufacturer. The plaintiff, Lisa Hyde, had a Bard filter placed in her inferior vena cava, which we'll refer to throughout the trial as the IVC, the vein that carries blood back to the heart. An IVC filter is intended to catch a blood clot before it reaches the heart or lungs. Defendants C.R. Bard, Inc., Bard Peripheral Vascular designed, manufactured and sold the filter.

Mrs. Hyde and her husband allege that the filter was defectively designed and that Defendants were negligent. They allege that Mrs. Hyde was injured by the filter and they seek to recover money from defendants to compensate for their injuries and to punish defendants for their allegedly wrongful conduct.

Defendants deny that their filter was defectively designed or that they were negligent ~~failed to warn of its risks. Defendants contend that the risks associated with the~~

~~Bard IVC filter are understood by the medical community and are considered by doctors when deciding whether to use them.~~ Defendants assert that they are not responsible for any injuries or damages suffered by Mr. and Mrs. Hyde. There are two defendants in this case, C.R. Bard, Inc., and Bard Peripheral Vascular. From time to time the parties may refer to them as Bard or BPV.

You should decide the case as to each defendant separately. Unless otherwise stated, the instructions apply to all of the parties. The evidence you are to consider in deciding what the facts are will consist of the sworn testimony of the witnesses, the exhibits that are admitted into evidence, any facts to which all of the lawyers have agreed, and those will be identified for you as agreed upon or stipulated facts, and any facts that I may instruct you to accept as proved.

In reaching your verdict, you may consider only the testimony and exhibits received in evidence. Certain things are not evidence and you may not consider them in deciding what the facts are. I will list them for you.

First, arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they may say in their opening statements this afternoon, their closing arguments at the end of the trial, or at other times is intended to help you interpret the evidence but it is not evidence.

If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls.

Second, questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules and

regulations of evidence. You should not be influenced by any lawyer's objection or by my ruling on it.

Third, testimony that is excluded or stricken or that I instruct you to disregard is not evidence and must not be considered. In addition, some evidence may be received only for a limited purpose. If I instruct to you consider certain evidence only for a limited purpose, you must do so and may not consider that evidence for any other purpose.

Finally, anything you may see or hear when the Court is not in session is not evidence. You are to decide the case solely on the evidence that will be received during the trial.

Evidence may be direct or circumstantial. Direct evidence is direct proof of a fact such as testimony by a witness about what that witness personally saw or heard or did. Circumstantial evidence is proof of one or more facts from which you can find another fact. You should consider both kinds of evidence. The law makes no distinction between the weight to be given to either direct or circumstantial evidence. It is for you to decide how much weight to give to any evidence.

There are Rules of Evidence that control what can be received into evidence during the trial. When a lawyer asks a question or offers an exhibit into evidence and a lawyer on the other side thinks that it is not permitted by the Rules of Evidence, that lawyer may object.

If I overrule the objection, the question may be answered or the exhibit received. If I sustain the objection, the question cannot be answered and the exhibit cannot be received.

Whenever I sustain an objection to a question, you must ignore the question and must not guess at what the answer might have been.

Sometimes, as I've already indicated, I may order that evidence be stricken from the record and that you disregard or ignore that evidence. That means that when you are deciding the case, you must not consider the stricken evidence for any purpose.

In deciding the facts in this case, you may have to decide which testimony to believe and which testimony not to believe. You may believe everything a witness says or part of it or none of it.

In considering the testimony of any witness, you may take into account the opportunity and ability of the witness to see or hear or know the things testified to, the witness's memory, the witness's manner while testifying, the witness's interest in the outcome of the case if any, the witness's bias or prejudice if any, whether other evidence contradicted the witness's testimony, the reasonableness of the witness's testimony in light of all of the evidence, and any other factors that bear on believability.

Sometimes a witness may say something that is not consistent with something else he or she said. Sometimes different witnesses will give different versions of what happened. People often forget things and make mistakes in what they remember. Also, two people may see the same event but remember it differently. You may consider these differences but do not decide the testimony is untrue just because it differs from other testimony.

However, if you decide that a witness has deliberately testified untruthfully about something important, you may choose not to believe anything that witness said. On the



other hand, if you think the witness testified untruthfully about some things but told the truth about others, you may accept the part you think is true and ignore the rest. The weight of the evidence as to a fact does not necessarily depend on the number of witnesses who testify about it. What is important is how believable the witnesses were and how much weight you think their testimony deserves.

I will now say a few words about your conduct as jurors. First, please keep an open mind throughout the trial and do not decide what the verdict should be until you and your fellow jurors have completed your deliberations at the end of the case.

Second, as I've already mentioned, because you must decide this case based only on the evidence received in the case and on my instructions as to the law that applies, you must not be exposed to any other information about the case or to the issues it involves during the course of your jury duty. Thus, until the end of the case or unless I instruct you otherwise, do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it.

This includes discussing the case in person, in writing, by phone or electronic means, via email, text messaging or any Internet chat room, blog, website or application including, but not limited to, Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other forms of social media.

This applies to communicating with your fellow jurors until I give you the case for deliberation, and it applies to communicating with everyone else, including your family members, your employer, the media or press, and the people involved in the trial although,

obviously, you can notify your family and your employer that you have been seated as a juror in this case and how long you expect the trial to last.

But if you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and report the contact to the Court immediately.

Because you will receive all of the evidence and legal instruction you properly may consider to return a verdict during this trial, do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it. Do not do any research such as consulting dictionaries, searching the Internet or using other reference materials and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in this case and do not use Internet programs or other devices to search for or view anyplace discussed during the trial.

Also, do not do any research about the case, the law, or the people involved including the parties, the witnesses, or the lawyers until you have been excused as jurors.

If you happen to read or hear anything touching on this case in the media, please turn away immediately and report the contact to me as soon as possible.

We have these rather detailed rules to protect each party's right to have this case decided only on the evidence that is presented here in court. Witnesses in court take an oath to tell the truth and the accuracy of their testimony is tested through the trial process.

If you do any research or investigation outside of the courtroom or gain any information through improper communication, then your verdict may be influenced by inaccurate, incomplete or misleading information that has not been tested by the trial

process. At least it will be based on information that these parties never had an opportunity to address during the trial. Each of the parties is entitled to a fair trial by an impartial jury and if you decide the case based on information not presented in the Court, you will have denied the parties a fair trial.

Please remember that you have taken an oath to follow these rules and it is very important that you do so. A juror who violates these restrictions jeopardizes the fairness of this trial and a mistrial could result that would require the entire trial process to start over again. If any of you is exposed to any outside information, please notify me immediately.

I urge you to pay close attention to the trial testimony as it is given. When you deliberate at the end of the case, you will not have a transcript of what was said. Even though we have a court reporter taking down everything that is said, it takes several days after a trial is over for the court reporter to go back and clean up that transcript and compare it with the recording and get it completely accurate. And that process won't be finished by the time you're deliberating so you will not have a transcript of the trial and as a result, we urge you to pay close attention to the evidence as it is given.

If you wish, you may take notes to help you remember the evidence. If you do take notes, please keep them to yourself until you go to the jury room to decide the case. Do not let note-taking distract you. When you leave each day or during a break, your notes should be left in the courtroom on your chair. Nobody will read your notes. Whether or not you take notes, you should rely on your own memory of the evidence. Notes are only to assist your memory. You should not be overly influenced by your notes or those of other jurors.

From time to time during the trial it may become necessary for me to talk to the lawyers outside of your hearing, either by having a conference here at the side of the bench as we did this morning or by calling a recess and excusing you from the courtroom. We will do our best to keep such conferences to a minimum. Please understand that the purpose of those conferences is not to keep relevant information from you, but to decide how certain evidence is to be treated under the Rules of Evidence and to avoid confusion and error.

I may not always grant a lawyer's request for a conference. Please do not consider my granting or denying a request for a conference as any indication of my opinion of what your verdict should be.

Trials proceed in the following way: First each side may make an opening statement. An opening statement is not evidence. It is simply an outline to help you understand what that party expects the evidence will show. The plaintiff will then present evidence and counsel for the defendant may cross-examine. Then the defendant may present evidence and counsel for the plaintiff may cross-examine.

After all of the evidence has been presented, I will give you instructions on the law that apply to this case and the attorneys will make their closing arguments. After that you will go to the jury room to deliberate on your verdict.

Counsel, are there any additions or corrections to the instructions?

## **Exhibit “B”**

**PROPOSED INSTRUCTION NO. 1**

Members of the Jury: Now that you have heard all of the evidence, it is my duty to instruct you on the law that applies to this case.

A copy of these instructions will be sent to the jury room for you to consult during your deliberations.

It is your duty to find the facts from all the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you whether you agree with it or not. And you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that you took an oath to do so.

Please do not read into these instructions or anything that I may say or do or have said or done as indicating that I have an opinion regarding the evidence or what your verdict should be.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 1.2 as modified by the Court in Booker and Jones

**PROPOSED INSTRUCTION NO. 2**

Although there are two defendants in this case, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., you should decide the case as to the two defendants jointly. As a result, in these instructions and in the verdict form, we will refer to defendants collectively as “Bard.” Unless otherwise stated, the instructions apply to both Bard and Mrs. Hyde.

Stipulated to in Booker and Jones

**PROPOSED INSTRUCTION NO. 3**

The evidence you are to consider in deciding what the facts are consists of:

1. the sworn testimony of the witnesses;
2. the exhibits that are admitted into evidence;
3. any facts to which the lawyers have agreed; and
4. any facts that I have instructed you to accept as proved.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 1.9



**PROPOSED INSTRUCTION NO. 4**

In reaching your verdict, you may consider only the testimony of the witnesses, the exhibits received into evidence, and facts to which the parties have agreed.

Certain things are not evidence, and you may not consider them in deciding what the facts are. I will list them for you:

1. Arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they have said in their opening statements, may say in closing arguments and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls.
2. Questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection or by the court's ruling on it.
3. Testimony that is excluded or stricken, or that you were instructed to disregard, is not evidence and must not be considered. In addition, some evidence is received only for a limited purpose; when I instruct you to consider certain evidence only for a limited purpose, you must do so and you may not consider that evidence for any other purpose.
4. Anything you may have seen or heard when the court was not in session is not evidence. You are to decide the case solely on the evidence received during the trial.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), ("9<sup>th</sup> Circuit Instruction") No. 1.10

**PROPOSED INSTRUCTION NO. 5**

Some exhibits admitted into evidence have been partially “redacted,” which means that certain contents of the exhibits have been blacked out or whited out. The parties and I have redacted information that is not properly admitted as evidence. You may give the unredacted information in any exhibit whatever weight you choose, but you must disregard the redacted information and must not speculate about what it might say.

Agreed to by the parties in Booker and Jones

**PROPOSED INSTRUCTION NO. 6**

You have heard testimony from a number of witnesses who testified to opinions and the reasons for their opinions. This opinion testimony is allowed because of the education or experience of those witnesses.

Such opinion testimony should be judged like any other testimony. You may accept it or reject it, and give it as much weight as you think it deserves, considering the witness's education and experience, the reasons given for the opinion, and all the other evidence in the case.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 2.13

**PROPOSED INSTRUCTION NO. 7**

Federal law prohibits current FDA employees from testifying in court regarding any function of the FDA, and prohibits current and former FDA employees from testifying about information acquired in the discharge of their official duties, without authorization of the Commissioner of the FDA. As a result, neither side in this case was able to present testimony from current FDA employees or former FDA employees regarding the discharge of their duties related to this case.

Previously requested by plaintiff in Booker and Jones

**PROPOSED INSTRUCTION NO. 8**

Certain charts and summaries not admitted into evidence have been shown to you in order to help explain the evidence in the case. These have been referred to as demonstrative exhibits. The demonstrative exhibits are only as good as the underlying evidence that supports them. You should, therefore, give them only such weight as you think the underlying evidence deserves.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 2.14

**PROPOSED INSTRUCTION NO. 9**

Certain charts and summaries have been admitted into evidence to illustrate information brought out in the trial. Charts and summaries are only as good as the testimony or other admitted evidence that supports them. You should, therefore, give these only such weight as you think the underlying evidence deserves.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 2.15

**PROPOSED INSTRUCTION NO. 10**

All parties are equal before the law and a corporation is entitled to the same fair and conscientious consideration by you as any party.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 4.1

**PROPOSED INSTRUCTION NO. 11**

Under the law, a corporation is considered to be a person. It can only act through its employees, agents, directors, or officers. Therefore, a corporation is responsible for the acts of its employees, agents, directors, and officers performed within the scope of authority.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 4.2



**PROPOSED CONCLUDING INSTRUCTION NO. 1**

Before you begin your deliberations, please elect one member of the jury as your presiding juror. The presiding juror will preside over the deliberations and serve as the spokesperson for the jury in court.

You shall diligently strive to reach agreement with all of the other jurors if you can do so. Your verdict must be unanimous.

Each of you must decide the case for yourself, but you should do so only after you have considered all of the evidence, discussed it fully with the other jurors, and listened to their views.

It is important that you attempt to reach a unanimous verdict but, of course, only if each of you can do so after having made your own conscientious decision. Do not be unwilling to change your opinion if the discussion persuades you that you should. But do not come to a decision simply because other jurors think it is right, or change an honest belief about the weight and effect of the evidence simply to reach a verdict.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 3.1

**PROPOSED CONCLUDING INSTRUCTION NO. 2**

Because you must base your verdict only on the evidence received in the case and on these instructions, I remind you that you must not be exposed to any other information about the case or to the issues it involves. Except for discussing the case with your fellow jurors during your deliberations:

Do not communicate with anyone in any way and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it. This includes discussing the case in person, in writing, by phone or electronic means, via email, via text messaging, or any internet chat room, blog, website or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other form of social media. This applies to communicating with your family members, your employer, the media or press, and the people involved in the trial. If you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and to report the contact to the court.

Do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it; do not do any research, such as consulting dictionaries, searching the Internet, or using other reference materials; and do not make any investigation or in any other way try to learn about the case on your own. Do not visit or view any place discussed in this case, the law, or the people involved – including the parties, the witnesses or the lawyers – until you have been excused as jurors. If you happen to reach or hear anything touching on this case in the media, turn away and report it to me as soon as possible.

As I've explained before, these rules protect each party's right to have this case decided only on evidence that has been presented here in court. Witnesses here in court take an oath to tell the truth, and the accuracy of their testimony is tested through the trial process. If you do any research or investigation outside the courtroom, or gain any information through improper communications, then your verdict may be influenced by inaccurate, incomplete or misleading information that has not been tested by the trial process. Each of the parties is entitled to a fair trial by an impartial jury, and if you decide the case based on information not presented in court, you will have denied the parties a fair trial. Remember, you have taken an oath to follow the rules, and it is very important that you follow these rules.

A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start over. If any juror is exposed to any outside information, please notify the court immediately.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 1.10

**PROPOSED CONCLUDING INSTRUCTION NO. 3**

The exhibits received in evidence that are capable of being displayed electronically will be provided to you in that form, and you will be able to view them in the jury room. A computer, projector, printer and accessory equipment will be available to you in the jury room.

A court technician will show you how to operate the computer and other equipment, how to locate and view the exhibits on the computer, and how to print the exhibits. You will also be provided with a paper list of all exhibits received in evidence. You may request a paper copy of any exhibit received in evidence by sending a note through the bailiff. If you need additional equipment or supplies or if you have questions about how to operate the computer or other equipment, you may send a note to the bailiff, signed by your presiding juror or by one or more members of the jury. Do not refer to or discuss any exhibit you are attempting to view.

If a technical problem or question requires hands-on maintenance or instruction, a court technician may enter the jury room with the bailiff present for the sole purpose of assuring that the only matter that is discussed is the technical problem. When the court technician or any non-juror is in the jury room, the jury shall not deliberate. No juror may say anything to the court technician or any non-juror other than to describe the technical problem or to seek information about operation of the equipment. Do not discuss any exhibit or any aspect of the case.

The sole purpose of providing the computer in the jury room is to enable you to view the exhibits received in evidence in this case. You may not use the computer for any other purpose. At my direction, technicians have taken steps to ensure that the computer does not permit access to the Internet or to any “outside” website, database, directory, game, or other material. Do not attempt to alter the computer to obtain access to such materials. If you discover that the computer provides or allows access to such materials, you must inform the court immediately and refrain from viewing such materials. Do not remove the computer or any electronic data from the jury room, and do not copy any such data.

**PROPOSED CONCLUDING INSTRUCTION NO. 4**

If it becomes necessary during your deliberations to communicate with me, you may send a note through the bailiff, signed by any one or more of you. No member of the jury should ever attempt to communicate with me except by a signed writing. I will not communicate with any member of the jury on anything concerning the case except in writing or here in the open court with the parties present. If you send out a question, I will consult with the lawyers before answering it, which may take some time. You may continue your deliberations while waiting for the answer to any question. Please remember that you are not to tell anyone – including the court – how the jury stands, whether in terms of vote count or otherwise, until after you have reached a unanimous verdict or have been discharged. Do not disclose any vote count in any note you may send out to the Court.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 3.3

**PROPOSED CONCLUDING INSTRUCTION NO. 5**

A verdict form has been prepared for you. [*Explain verdict form as needed*]. After you have reached unanimous agreement on a verdict, your foreperson should complete the verdict form according to your deliberations, sign and date it, and advise the bailiff that you are ready to return to the courtroom.

9<sup>th</sup> Circuit Manual of Model Jury Instructions for District Courts of the Ninth Circuit (2017), (“9<sup>th</sup> Circuit Instruction”) No. 3.5

## **Exhibit “C”**

**PROPOSED INSTRUCTION RE: PLAINTIFFS' CLAIMS**

Mr. and Mrs. Hyde assert five claims against Bard: (1) Strict Product Liability Based on Design Defect; (2) Negligent Design; (3) Negligence Per Se; (4) Loss of Consortium; and (5) Punitive Damages. I will instruct you on the law that applies to each of these claims. You should consider each claim separately.



**PROPOSED INSTRUCTION**  
**RE: WISCONSIN BURDEN OF PROOF**

Certain questions in the verdict form ask that you answer the questions “yes” or “no”. The party who wants you to answer the questions “yes” has the burden of proof as to those questions. This burden is to satisfy you by the greater weight of the credible evidence, to a reasonable certainty, that “yes” should be your answer to the verdict questions.

The greater weight of the credible evidence means that the evidence in favor of a “yes” answer has more convincing power than the evidence opposed to it. Credible evidence means evidence you believe in light of reason and common sense.

“Reasonable certainty” means that you are persuaded based upon a rational consideration of the evidence. Absolute certainty is not required, but a guess is not enough to meet the burden of proof.

WIS JI-CIVIL 200

**PROPOSED INSTRUCTION RE: DESIGN DEFECT**

To prove liability of (defendant manufacturer) for strict liability regarding design defect in this case, plaintiffs must establish all of the following five elements:

The product is defective because:

1. The foreseeable risks of harm posed by the product's design could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer, and the omission of the alternative design renders the product not reasonably safe.
2. The defective condition rendered the product unreasonably dangerous to persons or property.
3. The defective condition existed at the time the product left the control of the manufacturer.
4. The product reached the user or consumer without substantial change in the condition in which it was sold.
5. The defective condition was a cause of plaintiffs' damages.

WIS JI-CIVIL 3260-1

**PROPOSED INSTRUCTION RE: NEGLIGENT DESIGN**

The Plaintiffs are also asserting a claim for negligent design. It is the duty of a manufacturer to exercise ordinary care in the design of its product so as to render the product safe for its intended use and also safe for unintended uses which are reasonably foreseeable.

It is the further duty of the manufacturer, in the exercise of ordinary care, to make all reasonable and adequate tests and inspections of its product so as to guard against any defective condition which would render such product unsafe when used as it is intended to be used. A manufacturer is charged with the knowledge of its own methods of manufacturing its product and the defects in such methods, if any.

Failure of the manufacturer to perform any such duty constitutes negligence.

WIS JI-CIVIL 3240

**PROPOSED INSTRUCTION RE: TAXABILITY**

In determining the amount of damages for personal injuries, you must not include in the award, or add to it, any sum to compensate the plaintiff for state or federal income taxes, since damages received as an award for personal injuries are not subject to income taxes. You will not, of course, subtract from, or exclude from, your award of damages any amount because the plaintiff is not required to pay income taxes.

**PROPOSED INSTRUCTION RE: LIFE EXPECTANCY  
AND MORTALITY TABLES**

In determining future damages as a result of (plaintiff)'s injuries, you may consider the fact that at this time (plaintiff) is 54 years of age and has a life expectancy of 29.61 more years.

A mortality table which gives the expectancy of life of a person of (plaintiff)'s age was received in evidence as an aid in determining such expectancy. It is not, however, conclusive or binding upon you as to (plaintiff)'s actual or probable expectancy of life. Mortality tables are based upon averages, and there is no certainty that any person will live the average duration of life rather than a longer or shorter period. To determine the probable length of life of (plaintiff), you will consider all of the facts and circumstances established by the credible evidence bearing upon that subject.

**NOTE:** The defendants will agree to this instruction, depending on the evidence that is eventually produced.

**PROPOSED INSTRUCTION RE: PUNITIVE DAMAGES**

Punitive damages may be awarded, in addition to compensatory damages, if you find that the defendant acted maliciously toward the plaintiff or in an intentional disregard of the rights of the plaintiff.

A person's acts are malicious when they are the result of hatred, ill will, desire for revenge, or inflicted under circumstances where insult or injury is intended.

A person acts in an intentional disregard of the rights of the plaintiff if the person acts with the purpose to disregard the plaintiff's rights, or is aware that his or her acts are substantially certain to result in the plaintiff's rights being disregarded. Before you can find an intentional disregard of the rights of the plaintiff, you must be satisfied that the defendant's act or course of conduct was:

1. deliberate;
2. an actual disregard of the plaintiff's right to safety, health, or life, a property right, or some other right; and
3. sufficiently aggravated to warrant punishment by punitive damages.

A defendant's conduct giving rise to punitive damages need not be directed at the plaintiff seeking punitive damages. There is no requirement that the defendant intended to cause harm or injury to the plaintiff.

The purpose of punitive damages is to punish a wrongdoer or deter the wrongdoer and others from engaging in similar conduct in the future. Punitive damages are not awarded to compensate the plaintiff for any loss he or she has sustained. A plaintiff is not entitled to punitive damages as a matter of right. Even if you find that the defendant acted maliciously or in an intentional disregard of the plaintiff's rights, you do not have to award punitive damages. Punitive damages may be awarded or withheld at your discretion. You may not, however, award punitive damages unless you have awarded compensatory damages.

If you determine that punitive damages should be awarded, you may then award such sum as will accomplish the purpose of punishing or deterring wrongful conduct. Factors you should consider include:

1. the seriousness of the hazard to the public;
2. the profitability of the misconduct;

3. the attitude and conduct on discovery of the misconduct;
4. the degree of the manufacturer's awareness of the hazard and of its excessiveness;
5. the employees involved in causing or concealing the misconduct;
6. the duration of both the improper behavior and its concealment;
7. the financial condition of the manufacturer and the probable effect on the manufacturer of a particular judgment; and
8. the total punishment the manufacturer will probably receive from other sources.

### **SPECIAL VERDICT**

If you answered "yes" to question, \*answer this question:

Did (defendant) act maliciously toward (plaintiff) or in an intentional disregard of the rights of (plaintiff)?

Answer:

Yes or No

\* This blank refers to the question(s) to which a "yes" answer would support an award of punitive damages.

If you answered the preceding question "yes," answer this question:

What sum, if any, do you award against (defendant) as punitive damages?

Answer: \$\_\_\_\_\_

WIS JI-CIVIL 1707.2

### **Defendants' Position:**

The final portion beginning "special verdict" to the end should be deleted from the Jury Instructions, as the Judge will submit a separate jury verdict.

**Plaintiffs' Position:**

If the Judge determines that a Special Verdict Form is indicated, Plaintiffs will not object. However, Plaintiffs are not waiving their position set forth in Plaintiffs' Opposition to Defendants' Motion to Bifurcate Trial.



## **Exhibit ‘D’**

**PROPOSED INSTRUCTION RE: LOSS OF CONSORTIUM**

Mr. Hyde has asserted a claim for loss of consortium. “Consortium” involves the love and affection, the companionship and society, ~~the~~/and privileges of sexual relations, the comfort, aid, advice and solace, the rendering of material services, the right of support, and any other elements that normally arise in a close, intimate, and harmonious marriage relationship. A wrongful invasion, impairment, or deprivation of any of these rights, resulting from a disabling injury to a spouse, is a legal loss and a basis for damages to the other spouse harmed or deprived.

In ~~answer~~/evaluating this ~~question~~/claim, you should consider the nature, the form, and quality of the relationship that existed between the spouses up to the time of the injury. Based on that relationship, determine what sum will represent fair and reasonable compensation for any loss of consortium that was sustained by the deprived spouse as a result of the injury.

If you find that the loss will continue in the future, include in your answer damages for the period you are convinced it will continue to exist.

Compensation for loss of consortium, except as it relates to material services, is not measured by any rule of market value. Instead, it is measured on the basis of what you find is fair and reasonable compensation for the loss sustained by the deprived spouse. Compensation for material services is to be measured by what it would reasonably cost in the market for like services.

So as not to duplicate damages, do not include in your answer any allowance for loss of earnings or loss of earning capacity of the injured spouse. Those damages are dealt with in another question

WIS JI-CIVIL 1815

**NOTE:** Both parties agree a version of the above instruction should be given. Plaintiffs’ proposed language is highlighted in ~~yellow~~ above. Defendants’ proposed language is highlighted in ~~blue~~ above.

**Plaintiffs’ Objection:** Plaintiffs believe Wis JI-Civil 1815 should be read verbatim. A sentence stating that Mr. Hyde filed such a claim is redundant. The final sentence clarifies for the jury that loss of consortium is different from loss of earnings.

**Defendants’ Response:** Bard believes the introductory sentence added to the pattern instruction will simply assist the jury in understanding the context of the instruction that follows. Defendants believe the final sentence of the pattern instruction improperly

injects lost earnings into the case, when the Plaintiffs have previously conceded they are not seeking that element of damages.

**DEFENDANTS' PROPOSED INSTRUCTION RE: WISCONSIN BURDEN OF  
PROOF ON PUNITIVE DAMAGES**

The burden of proof regarding punitive damages rests upon the party contending that the answer to that question should be “yes.” The burden is to convince you by evidence that is clear, satisfactory, and convincing, to a reasonable certainty, that “yes” should be the answer to that question.

Clear, satisfactory, and convincing evidence is evidence which when weighed against that opposed to it clearly has more convincing power. It is evidence which satisfies and convinces you that “yes” should be the answer because of its greater weight and clear convincing power.

“Reasonable certainty” means that you are persuaded based upon a rational consideration of the evidence. Absolute certainty is not required, but a guess is not enough to meet the burden of proof.

WIS JI-CIVIL 205

**Plaintiff's Objection:** Plaintiffs object to this form of instruction as incomplete. However, Plaintiffs will agree to the use of this instruction, as modified, if Bard adds the entirety of the language in Wis JI-Civil 205:

“This burden of proof is known as the ‘middle burden.’ The evidence required to meet this burden of proof must be more convincing than merely the greater weight of the credible evidence, but may be less than beyond a reasonable doubt.”

**Defendants' Response:** The language cited by the plaintiffs is set forth in a parenthetical following the pattern instruction, and it is by no means clear that the language was intended to be part of the actual instruction. Additionally, the reference to “middle burden” is ambiguous and likely to mislead the jury.

**PLAINTIFFS' PROPOSED INSTRUCTION RE: PRODUCT LIABILITY: WIS.**  
**STAT. ' 895.047: VERDICT**  
**(FOR ACTIONS COMMENCED AFTER JANUARY 31, 2011)**

1. When (product) left the control of (Bard) and has reached the user or consumer without substantial change in the condition it was sold, was it in such a defective condition as to be unreasonably dangerous to a person
2. If you answered "yes" to Question No. 1, then answer this question. Otherwise, do not answer it. Was the defective condition a cause of the injury?
3. Was Defendant \_\_\_\_\_ negligent?
4. If you answered "yes" to the preceding question, then answer this question. Otherwise, do not answer it. Was Defendant \_\_\_\_\_'s negligence a cause of the injury?

**Defendants' Objection:** The Defendants object to including special verdict questions in the middle of the jury instructions, given that the jury will be afforded a separate jury verdict.

**Plaintiffs' Response:** If the Court determines that a separate Jury Verdict form is indicated, Plaintiffs agree to withdraw.

**DEFENDANTS' PROPOSED INSTRUCTION RE: DESIGN DEFECT**

A broad range of factors may be considered in determining whether an alternative design is reasonable and whether its omission renders a product not reasonably safe. The factors include, among others, the magnitude and probability of the foreseeable risks of harm, the instructions and warnings accompanying the product, and the nature and strength of consumer expectations regarding the product, including expectations arising from product portrayal and marketing.

Restatement (3d) of Torts, Product Liability, sec. 2, comment f.

**Plaintiffs' Objection:** Plaintiff objects to this instruction. Wisconsin has only adopted the Restatement (Third) provisions set forth in Wis. Stat 895.047(1), which do not include the one proposed here. Moreover, Wisconsin has not adopted the comments to the Restatement (Third). Defendants have not provided any authority suggesting Wisconsin has also adopted comments to the Third Restatement.

However, even if the Court decided to charge the jury with factors which may be considered with regard to an alternative design, any reference to "instructions and warnings" should be removed in accordance with the Court's order dismissing failure to warn claims.

**Defendants' Response:** This formulation comes directly from the comments of the Restatement (Third). As set forth in the Defendants' trial brief, when enacting Wis. Stat. 895.047 (1), the Wisconsin legislature clearly intended to adopt the standard for design defect set forth in the Restatement (Third). The comments to the Restatement provide helpful guidance on the factors pertinent to the terms (such as "alternative design" and "not reasonably safe" set forth in the standard. In addition, as the Restatement (Third) makes clear, the instructions and warnings provided with a product are a highly relevant factor in determining whether a product's design is defective, as they bear directly on whether the omission of an alternative design rendered the product not reasonably safe.

**DEFENDANTS' PROPOSED INSTRUCTION RE: RISK UTILITY**

The test for strict liability design defect requires you to weigh the risks and benefits of the filter. Products are not generically defective merely because they are dangerous. A reasonably designed product still carries with it elements of risk that must be protected against by the user or consumer since some risks cannot be designed out of the product at reasonable cost.

The balancing of risks and benefits in judging product design and marketing must be done in light of the knowledge of risks and risk-avoidance techniques reasonably attainable at the time of distribution.

Restatement (3d) of Torts, Product Liability, sec. 2, comment a.

**Plaintiffs' Objection:** Wisconsin has adopted only those Restatement (Third) provisions set forth in Wis. Stat 895.047(1), which do not include the one proposed here. Moreover, Wisconsin has not adopted the comments to the Restatement (Third). The proposed instruction misstates the law and Defendants have not provided any authority that Wisconsin has adopted sections and comments to the Third Restatement. The proposed instruction is also argumentative and misstates the law on reasonable alternative design.

**Defendants' Response:** This formulation comes directly from the comments of the Restatement (Third). As set forth in the Defendants' trial brief, when enacting Wis. Stat. 895.047 (1), the Wisconsin legislature clearly intended to adopt the standard for design defect set forth in the Restatement (Third). The comments to the Restatement provide helpful guidance on the factors pertinent to the terms (such as "alternative design" and "not reasonably safe" set forth in the standard.

**DEFENDANTS' PROPOSED INSTRUCTION RE: INDUSTRY PRACTICE**

Industry practice may be relevant to whether the omission of an alternative design rendered the product not reasonably safe.

Restatement (3d) of Torts, Product Liability, sec. 2, comment d.

**Plaintiffs' Objection:** This instruction is a misstatement of Wisconsin law and Defendants have not provided any authority that Wisconsin's product liability statutory scheme contemplates that Restatement (Third) sections or comments a source of authority. Wisconsin has adopted only those Restatement (Third) provisions set forth in Wis. Stat. 895.047, which do not include the one proposed here. Moreover, Wisconsin has not adopted the comments to the Restatement (Third). Furthermore, Defendants have objected to Plaintiffs' proposal of Wis JI-Civil 1019.

**Defendants' Response:** This formulation comes directly from the comments of the Restatement (Third). As set forth in the Defendants' trial brief, when enacting Wis. Stat. 895.047 (1), the Wisconsin legislature clearly intended to adopt the standard for design defect set forth in the Restatement (Third). The comments to the Restatement provide helpful guidance on the factors pertinent to the terms (such as "alternative design" and "not reasonably safe" set forth in the standard.



**DEFENDANTS' PROPOSED INSTRUCTION RE: COMPLIANCE**

There was evidence received that at the time of sale, the product complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency. From this evidence, a rebuttable presumption arises that the product was not defective. However, there is also evidence which may be believed by you that the product is defective. You must resolve this conflict. Unless you are satisfied by the greater weight of the credible evidence, to a reasonable certainty, that it is more probable than not that the product was defective, you should find that the product was not defective.

WIS JI-CIVIL 3260.1

**Plaintiffs' Objection:** This instruction and defense are not available to Defendants. *See* Order, July 26, 2018 (Doc. 12007), at 10-12 (“Because the 510(k) clearance process focuses on equivalence, not safety, the presumption of non-defectiveness afforded by §895.047(3)(b) is not applicable.”). Defendants should withdraw this proposed instruction.

**Defendants' Response:** The Defendants acknowledge the Court's ruling regarding this issue when addressing the Defendants' summary judgment motion. However, the Defendants respectfully submit that the Court engrafted a limitation on the statute that is not supported by the plain language of the provision. Specifically, the Court suggested that only compliance with “safety” standards are relevant under this defense, when the statute does not contain that qualification, rather speaking only in terms of “relevant standards,” conditions, or specifications adopted or approved by a federal or state law or agency.” Consistent with that language, the Defendants will urge the Court at the appropriate time to instruct the jury regarding the presumption set forth in this Wisconsin statute.

**DEFENDANTS' PROPOSED INSTRUCTION**  
**RE: INHERENT CHARACTERISTIC**

The plaintiffs may not recover on their strict liability claim if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.

Wis. Stat. § 895.047(3)(d)

**Plaintiffs' Objection:** Plaintiffs object to this instruction which is not based on or found in Wis JI-CIVIL 3260.1. The proposed objection is argumentative and not applicable to the facts of the case. There is no evidence that an ordinary person like Plaintiff or even her doctor had the ability or knowledge to recognize, understand, or appreciate the unreasonable dangers associated with Bard filters and the risks of injuries caused by failures such as migration, tilt, penetration or fracture.

**Defendants' Response:** This is an accurate statement of Wisconsin law, and the Defendants believe they are entitled to have the jury instructed on the principle. The Wisconsin pattern instruction regarding strict liability product design, is skeletal, at best, and the absence of language covering this clear rule in no way suggests an instruction on the principle would be improper.

**DEFENDANTS' PROPOSED INSTRUCTION RE: CAUSATION**

If you find that the filter was defectively or negligently designed, you must also decide whether that design caused the injury. An injury may have more than one cause. The design caused the injury if it was a substantial factor in producing the injury. An injury may be caused by one cause or by the combination of multiple causes.

WIS JI-CIVIL 1500

**Plaintiffs' Objections:** Defendants' proposed instruction misstates the language in Wis JI-Civil 1500. Plaintiffs agree that a form of Wis JI-Civil 1500 must be given to the jury. However, the instruction must incorporate each of Plaintiffs' liability claims including strict liability design, negligent design, and negligence *per se*.

**Defendants' Response:** For the reasons set forth in the pre-trial order, Defendants submit that Plaintiffs negligence per se claim is preempted, and hence should be excluded from these instructions.

**PLAINTIFFS' INSTRUCTION RE CAUSE: NORMAL RESPONSE**

If a person's negligence creates a situation that triggers an act by (another person) (an animal) which is a normal response to the situation created by the negligence, you may find that any injuries that result from the responsive act were caused by the original negligence.

You must decide whether an act causing any (plaintiff)'s injuries was a normal response to the situation created by the original negligence and, whether injuries, therefore, should be attributed to that negligence.

**Defendants' Objection:** The defendants object to this instruction because it is not adjusted to the evidence in this case, and is completely out of context to the circumstances giving rise to the Plaintiffs' claims. The instruction appears to be addressing a reflexive response to a situation where the response in and of itself causes an injury. It is difficult to see how that scenario has any bearing, even remotely, on Mrs. Hyde's situation.

**PLAINTIFFS' INSTRUCTION RE NEGLIGENCE: DEFINED**

A person is negligent when (he) (she) fails to exercise ordinary care. Ordinary care is the care which a reasonable person would use in similar circumstances. A person is not using ordinary care and is negligent, if the person, without intending to do harm, does something (or fails to do something) that a reasonable person would recognize as creating an unreasonable risk of injury or damage to a person or property. (For the violation of a safety statute, see Wis JI-Civil 1009.)

**Defendant's Objection:** The definition of negligence is subsumed with Wis JI-Civil 3240, which defines negligence specifically for product liability claims. All parties have agreed to the use of that Instruction, which is more appropriate for this case than the general negligence instruction.

**Plaintiffs' Response:** This instruction defines negligence and further defines ordinary care. Both legal concepts are referred to in Wis JI- Civil3240. Furthermore, the Wisconsin Jury Instructions are devoid of any comment that this instruction has been subsumed by another instruction. It is different from Wis JI-Civil 3240 and accurately states the law in Wisconsin. Further, the definition provides substantive instruction on the law jurors must follow and apply.

**PLAINTIFFS' INSTRUCTION RE NEGLIGENCE:**  
**VIOLATION OF SAFETY STATUTE**

Violation of a safety statute or regulation is negligence as that term is used in the verdict questions and my instructions. Plaintiffs claim that defendants violated one or more of the following safety statutes or regulations which provide as follows:

21 C.F.R. 803

§ 803.1 Scope. (a) This part establishes requirements for medical device reporting. Under this part, device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, and must establish and maintain adverse event files. Manufacturers are also required to report certain device malfunctions and submit an annual report to FDA certifying that the correct number of medical device reports were filed during the previous 12-month period or, alternatively, that no reports were required during that same time period. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(d) Caused or contributed means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of: (1) Failure; (2) Malfunction; (3) Improper or inadequate design; (4) Manufacture; (5) Labeling; or (6) User error

21 C.F.R. 806.1

(a) This part implements the provisions of section 519(g) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and importers to report promptly to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

(b) The following actions are exempt from the reporting requirements of this part:

(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.

21 C.F.R. 820.250

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

21 U.S.C. §321

(h) The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is— (2) intended for .....the cure, mitigation, treatment, or prevention of disease, in man or other animals

21 C.F.R. 820.100

Sec. 820.100 Corrective and preventative action.

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

21 C.F.R. 820.198

Sec. 820.198 Complaint files.

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

(1) All complaints are processed in a uniform and timely manner;

(2) Oral complaints are documented upon receipt; and

(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of:



- (1) Whether the device failed to meet specifications;
  - (2) Whether the device was being used for treatment or diagnosis; and
  - (3) The relationship, if any, of the device to the reported incident or adverse event.
- (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:
- (1) The name of the device;
  - (2) The date the complaint was received;
  - (3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
  - (4) The name, address, and phone number of the complainant;
  - (5) The nature and details of the complaint;
  - (6) The dates and results of the investigation;
  - (7) Any corrective action taken; and
  - (8) Any reply to the complainant.
- (f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.
- (g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:
- (1) A location in the United States where the manufacturer's records are regularly kept; or
  - (2) The location of the initial distributor.

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

(1) All complaints are processed in a uniform and timely manner;

(2) Oral complaints are documented upon receipt; and

(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of:

(1) Whether the device failed to meet specifications;

(2) Whether the device was being used for treatment or diagnosis; and

(3) The relationship, if any, of the device to the reported incident or adverse event.

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any unique device identifier (UDI) or Universal Product Code (UPC), and any other device identification(s) and control number(s) used;

(4) The name, address, and phone number of the complainant;

(5) The nature and details of the complaint;

(6) The dates and results of the investigation;

(7) Any corrective action taken; and

(8) Any reply to the complainant.

(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

(1) A location in the United States where the manufacturer's records are regularly kept; or

(2) The location of the initial distributor.

21 U.S.C. § 331

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded

21 U.S.C. §352.

A drug or device shall be deemed to be misbranded—

(a) False or misleading label

(1) If its labeling is false or misleading in any particular.

If you determine that defendant violated this safety (statute) or (regulation) the violation is negligence.

REFERENCE: Wis JI-Civil 1009

**Defendants’ Objection:** The defendants object to the plaintiffs’ negligence per se charge, as it demonstrates that the plaintiffs’ negligence per se claim is predicated entirely on allegations that Bard violated the Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 et seq., and related regulations. As this Court held in Booker, such a claim is impliedly preempted under 21 U.S.C. § 337(a) because no private right of action exists under the FDCA, and all proceedings to enforce or restrain violations of the statute must be brought by the FDA. (Doc. 8874).

**Plaintiffs’ Response:** Bard is incorrect that *Buckman* preempts Plaintiffs’ negligence *per se* claims. Defendant has cited *Buckman* and *Perez, supra*, however those cases are distinguishable because the present claims are based upon Wisconsin common law negligence and not solely on the FDCA regulations. To support their claims of negligence *per se*, Plaintiffs will establish that Defendant negligently failed to design IVC filters in a manner that complied with the previously cited regulations. Plaintiffs are not attempting to enforce federal regulations and are not alleging any fraud on the FDA. Rather they are relying on the regulations to establish the standard of care in the negligence claim. Bard breached duties to Plaintiffs, not the FDA.

The distinction between *Buckman* and the doctrine of implied preemption to allow a negligence *per se* claim in Wisconsin was explained well in *Garross v Medtronic, Inc.*, 77 F. Supp. 3d 809 (E.D. Wis. 2015), and *Marvin v Zydus Pharmaceuticals. (USA), Inc.*, 203 F. Supp. 3d 985 (W.D. Wis. 2016). In *Garross* the Court stated:

Nor are Plaintiffs’ claims impliedly preempted. None of the claims arise solely from a violation of federal law. Rather, each arises from an independent, well-recognized duty owed under state law. *See Buckman*, 531 U.S. at 353, 121 S.Ct. 1012 (distinguishing between claims arising “from the manufacturer’s alleged failure to use reasonable care” and claims arising “solely” from a violation of a federal requirement); *Bausch*, 630 F.3d at 558 (holding that claims which allege a “breach of a well-recognized duty owed to [plaintiff] under state law” are not impliedly preempted) *Id* at 816.

*Garross*, 77 F. Supp. 3d at 816. Wisconsin Federal Courts have found that violations of FDA regulations may constitute negligence *per se* since they are safety statutes. *See Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 964 (E.D. Wis. 1981), *amended*, 532 F. Supp. 211 (E.D. Wis. 1981).

The Wisconsin Supreme Court has also explained:

[A] safety statute merely establishes a minimum standard of care and the

conduct, even though sanctioned or in conformity with the statute, is not thereby necessarily relieved of conforming to the common-law requirements of ordinary care. In any event the establishment of a statutory definition of negligence per se does not thereby result in a preemption of the entire negligence question. There remains the question of possible common-law negligence.

*Hoffmann v. Wisconsin Elec. Power Co.*, 262 Wis. 2d 264, 278 (Wis. 2003) (citations omitted). Moreover, a “statute does not change the common law unless the legislative purpose to do so is clearly expressed in the language of the statute.” *Hoffman*, 262 Wis.2d at 278; *see also Fuchsgruber v. Custom Accessories, Inc.*, 244 Wis. 2d 758 (Wis. 2001) (stating that to “accomplish a change in the common law, the language of the statute must be clear, unambiguous, and peremptory.”) (citations omitted).

Blanchard et al., v. Terpstra et al., 37 Wis.2d 292, 299 (1967).

**DEFENDANTS' PROPOSED INSTRUCTION RE: DAMAGES**

In considering the amount to be awarded as damages, if any, the burden of proof rests upon each person claiming damages to satisfy you by the greater weight of the credible evidence, to a reasonable certainty, that the person sustained damages with respect to element or elements mentioned in the question and the amount of the damages. The greater weight of the credible evidence means that the evidence in favor of an answer has more convincing power than the evidence opposed to it. Credible evidence means evidence you believe in light of reason and common sense. "Reasonable certainty" means that you are persuaded based upon a rational consideration of the evidence. Absolute certainty is not required, but a guess is not enough to meet the burden of proof. The amount inserted by you should reasonably compensate the person for the damages from the accident.

Determining damages for pain and suffering cannot always be made exactly or with mathematical precision; you should award as damages amounts which will fairly compensate Plaintiffs for their injuries.

The amount you insert in answer to each damage question is for you to determine from the evidence. What the attorneys ask for in their arguments is not a measure of damages. The opinion or conclusions of counsel as to what damages should be awarded should not influence you unless it is sustained by the evidence. Examine the evidence – carefully and dispassionately – and determine your answers from the evidence in the case.

WIS JI-CIVIL 1700

**Plaintiffs' Objection:** The first sentence in Defendants' proposed instruction misstates the language of Wis JI-Civil 1700. Plaintiffs believe the language should track verbatim the language of Wis JI-Civil 1700 provided below.

**Defendants' Response:** A number of pattern Wisconsin jury instructions contemplate presenting the jury with special interrogatories in the course of the jury instructions. In that regard, Wis JI-Civil 1700 is written so as to read the jury a series of special interrogatories concerning various elements of damages. Since this Court is presumably not going to follow that procedural format, the Defendants extracted the key substantive points from Wis JI-Civil 1700 to craft this modified instruction. In contrast to this revised version, the verbatim instruction urged by the Plaintiffs will only confuse the jury.

**PLAINTIFFS' INSTRUCTION RE: DAMAGES: GENERAL**

The verdict contains the following damage questions, numbered through .

[Read question(s).]

**[Note: Select the following paragraphs which are appropriate.]**

[I have answered question(s) \_\_\_\_\_ because the parties have agreed on the amount(s) to be inserted. You should not conclude from the fact I have answered (this) (these) question(s) as to the amount of damages that any party has admitted fault or that any party may be responsible for the amount(s) inserted. Finally, you should not assume that because I have answered (this) (these) question(s), that a party already has or necessarily will recover (this) (these) amount(s). Parties, may, as here, agree on an amount of damages without admitting they are responsible for the damages.]

[You must answer the damage question(s) no matter how you answered any of the previous questions in the verdict. The amount of damages, if any, found by you should in no way be influenced or affected by any of your previous answers to questions in the verdict.]

[In answering the damage question(s), completely disregard any percentages which you may have inserted as your answers to the subdivisions of question \_\_\_\_\_, the comparative negligence question.]

[In answering the damage questions, be careful not to include or duplicate in any answer amounts included in another answer made by you or me.]

[Your answer(s) to the damage question(s) should not be affected by sympathy or resentment (or by the fact that one (or more) of the parties from whom damages are sought (is an insurance corporation) (are insurance corporations)); nor should you make any deductions because of a doubt in your minds as to the liability of any party to this action.]

**Plaintiffs' Response:** This is the verbatim instruction set forth in Wis JI-Civil 1700

**DEFENDANTS' PROPOSED INSTRUCTION RE: DAMAGES**

If you find that Defendants are liable, you must determine what sum of money will fairly and reasonably compensate Mrs. Hyde for any personal injuries she sustained as a result of the accident. Your answer to this question should be the amount of money that will fairly and reasonably compensate plaintiff for the personal injuries she has suffered to date and is reasonably certain to suffer in the future as a result of the accident.

Personal injuries include pain, suffering, and disability (disfigurement) which means any physical pain, worry, distress, embarrassment and humiliation which Mrs. Hyde has suffered in the past and is reasonably certain to suffer in the future. You should consider also to what extent her injuries have impaired and will impair her ability to enjoy the normal activities, pleasures, and benefits of life. Consider the nature of her injuries, the effect produced by her injuries in the past, and the effect the injuries are reasonably certain to produce in the future, bearing in mind her age, prior mental and physical condition, and the probable duration of her life.

Personal injuries can also include health care and treatment expenses. If you are satisfied that Mrs. Hyde will require health care and treatment in the future for injuries sustained as a result of the accident include in your answer to this question the sum of money that will reasonably and necessarily be expended in the future for that care and treatment.

WIS JI-CIVIL 1750.2

**Plaintiffs' Objection:** As stated in Plaintiffs' response to Defendants' objection to Plaintiffs' proposed jury instruction No. 8, Plaintiffs do not agree Wis JI-Civil 1750.2 is preferred as a substantive instruction. Most Wisconsin Courts have divided each element of damages into separate inquiries. Further, Wis JI-Civil 1756 is in accord with recommendations of the Committee on Civil Jury Instructions. "The Committee does not generally recommend the use of a single verdict question to determine damages where the plaintiff seeks to recover different types of damages for personal injuries." *See* Comment to 1750.2 in Wisconsin Jury Instructions (2018).

**Defendants' Response:** The comment cited by the Plaintiffs above pertains to the procedural verdict forms favored in Wisconsin, and not to the jury instructions. This instruction is a concise summary of all of the elements of damages sought by the Plaintiffs. The lengthier instructions urged by the Plaintiffs will merely confuse the jury and also unduly emphasize and repeat various damage claims.



**DEFENDANTS' PROPOSED INSTRUCTION RE: PRESENT VALUE**

In determining the amount of damages for medical expenses incurred by Mrs. Hyde in the future, you must determine the present worth in dollars of the future damages.

A lump sum of money received today may be worth more than the same sum paid in installments over a period of months or years. This is because a sum received today can be invested and earn money at current interest rates. By making a reduction for the earning powers of money, your answer will reflect the present value in dollars of an award of future damages.

This instruction which asks you to reduce future damages to present value does not apply to that portion of future damages which represents future pain and suffering.

WIS JI-CIVIL 1796

**Plaintiffs' Response:** Plaintiff understands that this instruction may be given but thinks it is imprudent. Medical costs have been increasing far more each year than the current yearly rate of interest to invest that same money. However if Defendant wishes to include this instruction, Plaintiffs do not object.

**DEFENDANTS' PROPOSED INSTRUCTION RE: PUNITIVE DAMAGES**

You may not use punitive damages to punish defendants for harming others. Evidence of actual harm to nonparties may help to show that the defendants' conduct that harmed plaintiff also posed a substantial risk to the general public, and so was particularly reprehensible, however, you may not use punitive damages to punish defendants directly for harm to those nonparties.

WIS JI-CIVIL 1702 (suggested language); Kehl v. Economy Fire & Casualty Co., 433 N.W. 2d 279, 147 Wis. 2d 531 (1988).

**Plaintiffs' Objection:** Argumentative. Wis JI-Civil 1707.2 covers the law of punitive damages in Wisconsin.

**Defendants' Response:** This statement is set forth in the comments to Wis JI-CIVIL 1702, and those comments specifically suggest utilizing this language when appropriate in a particular case. Bard submits this accurate statement of Wisconsin law is particularly needed in a case, like the present one, where the Plaintiffs seek to present a large volume of evidence concerning earlier generation products and unrelated injuries allegedly caused by those products.

**PLAINTIFFS' PROPOSED INSTRUCTION RE PERSONAL INJURIES: PAST  
HEALTH CARE EXPENSES**

(Question \_\_\_\_\_) (Subdivision \_\_\_\_\_ of question \_\_\_\_\_) asks what sum of money will fairly and reasonably compensate (plaintiff) for past health care services.

You will insert as your answer to this (question) (subdivision) the sum of money you find has reasonably and necessarily been incurred from the date of the accident up to this time for the care of the injuries sustained by (plaintiff) as a result of the accident.

Billing statements (which may include invoices) for health care services (plaintiff) has received since the accident have been admitted into evidence.

**[NOTE: Use the following paragraph if no evidence has been received disputing the value, reasonableness, or necessity of health care services provided to plaintiff:** These billing statements establish the value, reasonableness, and necessity of health care services provided to (plaintiff). You must still determine whether the health care services were provided for the injuries sustained by (plaintiff) as a result of the accident.]

**[NOTE: Use the following paragraph if evidence has been received disputing the value, reasonableness, or necessity of health care services provided to plaintiff:** The party challenging the (value of) (reasonableness and necessity of) (plaintiff)'s past health care services has the burden to prove they were not (reasonable in amount) (reasonably and necessarily provided to care for (plaintiff)). Unless you are satisfied by the greater weight of the credible evidence, to a reasonable certainty, that the billing statements (were not reasonable in amount) (do not reflect health care services reasonably and necessarily provided to care for (plaintiff)), you must find (the billing statements reflect the reasonable value of the health care services) (the health care services reflected in the billing statements were reasonably and necessarily provided to care for (plaintiff)). You must still determine whether the health care services were provided for the injuries sustained by (plaintiff) as a result of the accident.]

**Defendants' Objection:** The defendants' object to this Instruction because the subject matter is already covered by Wis JI-CIVIL 1750.2, which has been proposed by the defendants. That Pattern Instruction is a much more efficient and concise explanation of damages than the multiple separate instructions proposed by the plaintiffs.

**Plaintiffs' Response:** Plaintiffs do not agree Wis JI-Civil 1750.2 is preferred as a substantive instruction. Most Wisconsin Courts have divided each element of damages into separate inquires. Further, Wis JI-Civil 1756 is in accord with recommendations of the Committee on Civil Jury Instructions. "The Committee does not generally recommend the use of a single verdict question to determine damages where the plaintiff seeks to recover different types of damages for personal injuries." *See* Comment to 1750.2 in Wisconsin Jury Instructions (2018).

**PLAINTIFFS' INSTRUCTION RE PERSONAL INJURIES:**  
**FUTURE HEALTH CARE EXPENSES**

(Question \_\_\_\_\_) (Subdivision \_\_\_\_\_ of question \_\_\_\_\_) asks what sum of money will fairly and reasonably compensate plaintiff for future health care services. If you are satisfied that plaintiff will require health care services in the future for injuries sustained as a result of (e.g. the accident), you will insert as your answer to this question (subdivision) the sum of money you find will reasonably and necessarily be incurred in the future to care for (plaintiff).

**Defendants' Objection:** The defendants' object to this Instruction because the subject matter is already covered by Wis JI-CIVIL 1750.2, which has been proposed by the defendants. That Pattern Instruction is a much more efficient and concise explanation of damages than the multiple separate instructions proposed by the plaintiffs.

**Plaintiffs' Response:** Plaintiffs do not agree Wis JI-Civil 1750.2 is preferred as a substantive instruction. Most Wisconsin Courts have divided each element of damages into separate inquiries. Further, Wis JI-Civil 1756 is in accord with recommendations of the Committee on Civil Jury Instructions. "The Committee does not generally recommend the use of a single verdict question to determine damages where the plaintiff seeks to recover different types of damages for personal injuries." *See* Comment to 1750.2 in Wisconsin Jury Instructions (2018).

**PLAINTIFFS' PROPOSED INSTRUCTION RE: PERSONAL INJURIES: PAST PAIN, SUFFERING, AND DISABILITY (DISFIGUREMENT)**

(Question \_\_\_\_\_) (Subdivision \_\_\_\_\_ of Question \_\_\_\_\_) asks what sum of money will fairly and reasonably compensate (plaintiff) for past pain, suffering, and disability (disfigurement).

Your answer to this (question) (subdivision) should be the amount of money that will fairly and reasonably compensate (plaintiff) for the pain, suffering, and disability (disfigurement) (she) has suffered from the date of the accident up to this time as a result of the accident.

Pain, suffering, and disability (disfigurement) includes any physical pain, humiliation, embarrassment, worry and distress which (plaintiff) has suffered in the past. You should consider to what extent (his) (her) injuries impaired (her) ability to enjoy the normal activities, pleasures, and benefits of life.

**Defendants' Objection:** The defendants' object to this Instruction because the subject matter is already covered by Wis JI-CIVIL 1750.2, which has been proposed by the defendants. That Pattern Instruction is a much more efficient and concise explanation of damages than the multiple separate instructions proposed by the plaintiffs.

**Plaintiffs' Response:** Plaintiffs do not agree Wis JI-Civil 1750.2 is preferred as a substantive instruction. Most Wisconsin Courts have divided each element of damages into separate inquiries. Further, Wis JI-Civil 1766 is in accord with recommendations of the Committee on Civil Jury Instructions. "The Committee does not generally recommend the use of a single verdict question to determine damages where the plaintiff seeks to recover different types of damages for personal injuries." *See* Comment to 1750.2 in Wisconsin Jury Instructions (2018).

**PLAINTIFFS' PROPOSED INSTRUCTION RE: PERSONAL INJURIES:  
FUTURE PAIN, SUFFERING, AND DISABILITY (DISFIGUREMENT)**

(Question \_\_\_\_\_) (Subdivision \_\_\_\_\_ of question \_\_\_\_\_) asks what sum of money will fairly and reasonably compensate (plaintiff) for future pain, suffering, (and) disability, (and disfigurement).

If you are satisfied that (plaintiff) will endure pain, suffering, (and) disability, (and disfigurement) in the future as a result of the accident, you will insert as your answer to this (question) (subdivision) the sum of money you find will fairly and reasonably compensate (plaintiff) for this future pain, suffering, (and) disability, (and disfigurement).

Pain, suffering, (and) disability, (and disfigurement) includes:

- physical pain
- worry
- distress
- embarrassment
- humiliation

In answering this damage question, you should consider the following factors:

- the extent (plaintiff)'s injuries have impaired and will impair (his) (her)ability to enjoy the normal activities, pleasures, and benefits of life;
- the nature of (plaintiff)'s injuries;
- the effect the injuries are reasonably certain to produce in the future bearing in mind (plaintiff)'s age, prior mental and physical condition, and the probable duration of (his) (her) life.

**Defendants' Objection:** The defendants' object to this Instruction because the subject matter is already covered by Wis JI-CIVIL 1750.2, which has been proposed by the defendants. That Pattern Instruction is a much more efficient and concise explanation of damages than the multiple separate instructions proposed by the plaintiffs.

**Plaintiffs' Response:** Plaintiffs do not agree Wis JI-Civil 1750.2 is preferred as a substantive instruction. Most Wisconsin Courts have divided each element of damages into separate inquiries. Further, Wis JI-Civil 1767 is in accord with recommendations of the Committee on Civil Jury Instructions. "The Committee does not generally recommend the use of a single verdict question to determine damages where the plaintiff

seeks to recover different types of damages for personal injuries.” *See* Comment to 1750.2 in Wisconsin Jury Instructions (2018).